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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.       | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------------|------------------|
| 10/618,134      | 07/11/2003  | Gerold Schuler       | 100725-37 / Kreisler 1108 | 4429             |

27384 7590 11/02/2005

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EXAMINER

JALLA, SANJOO

ART UNIT PAPER NUMBER

1644

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/618,134

Applicant(s)

SCHULER ET AL.

Examiner

Sanjoo Shree Jalla

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07/11/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1644

#### DETAILED ACTION

Claims 15-18 and 26-28 are objected to as nonstatutory "USE" claims hence they are withdrawn from restriction.

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-3, 12, 14, 24 and 25 drawn to isolated CD4<sup>+</sup>CD25<sup>-</sup> T cells, classified in Class 424, subclass 154.1.

II. Claims 4, 5, 12-14, 24 and 25 drawn to isolated Tr1-like regulatory T cells, classified in Class 424, subclass 577.

III. Claims 6-8, drawn to a method for expanding CD4<sup>+</sup>CD25<sup>-</sup> T cells or Tr1-like regulatory T cells, classified in Class 424, subclass 153.1.

IV. Claims 9-11, drawn to a method of producing Tr1-like regulatory cells, classified in Class 424, subclass 173.1.

V. Claim 19 drawn to a method for adoptive transfer therapy, employing Tr1-like regulatory cells, classified in Class 435, subclass 7.25.

VI. Claims 20-23 drawn to a method for preparing CD4<sup>+</sup>CD25<sup>-</sup> T cells, classified in Class 424, subclass 577.

VII. Claims 20-23 drawn to a method for preparing Tr1-like regulatory T cells, classified in Class 424, subclass 577.

2. Groups I and II are unrelated products. CD4<sup>+</sup>CD25<sup>-</sup> T cells or Tr1-like regulatory T cells, differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

3. Groups III-VII are different methods. In the instant case the different inventions are drawn to methods comprising different method steps, different reagents, resulting in different end points. For example, the steps used in the method of expanding CD4<sup>+</sup>CD25<sup>-</sup> T cells (stimulating T cells with T cell stimulating agent or with APC's) of group III are distinct from the steps required for the method of producing the Tr1-like regulatory cells (anergizing CD4<sup>+</sup>CD25<sup>-</sup> T cells by contacting CD4<sup>+</sup>CD25<sup>-</sup> T cells with

Art Unit: 1644

an anergic state inducing agent) in group IV. Furthermore, the steps and reagents used are different in the method of group VI and VIII, where CD4<sup>+</sup>CD25<sup>-</sup> T cells and Tr1- like regulatory T cells respectively are prepared as compared to groups III where either the T cells are expanded and IV where Tr1-like regulatory cells are produced. Further, method of adoptive transfer therapy of group V (injecting back into patients enriched Tr1-like regulatory cells) is distinct in method steps and reagents used for preparing CD4<sup>+</sup>CD25<sup>-</sup> T cells like regulatory T cells of group VI (activating CD4<sup>+</sup>CD25<sup>-</sup> T cells with an antigen presenting cell).

4. Groups I-II and III-VIII are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, ratio of suppressor Tr1-like regulatory T cells and allergen specific Th2 effector cells can be used to determine the development of a healthy or an allergic immune response. Further, CD4<sup>+</sup>CD25<sup>-</sup> T cells can be used for induction of anergy *in vitro* through their interaction with activated CD4<sup>+</sup>CD25<sup>+</sup> T cells and in the presence of co-stimulation.

5. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Art Unit: 1644

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art because of their recognized divergent subject matter. Further, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

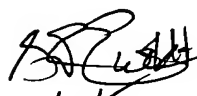
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Sanjoo S Jalla whose telephone number is 571-272-4453. The examiner can normally be reached Monday through Friday from 8:30-5pm.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on

Art Unit: 1644

access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sanjoo S. Jalla, Ph.D.  
Patent Examiner  
Technology Center 1600

  
10/20/05  
**G.R. EWOLDT, PH.D.**  
**PRIMARY EXAMINER**